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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,562	10/24/2000	Dr. Max Schaldach	7040-5	1946

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,562

Applicant(s)

SCHALDACH ET AL. *Ch*

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The Examiner requests translations of the non-English documents (AF-AI) contained in the Information Disclosure Statement filed October 24, 2000.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitations of claims 2-16 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Specifically, the drawings must show a stent having coating islands equally spaced apart, as well as coating islands of varying sizes.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because grammatical errors exist.

Specifically, the phrase "In order now immediately after dilation" is unclear (line 1 of P0004), in line 2 of P0022 "regions 8 through 6" should be "regions 8 through 16", and line 5 of P0022 should read "coating islands 18". Correction is required. See MPEP § 608.01(b).

4. The substitute specification filed June 12, 2002 has not been entered because it does not conform to 37 CFR 1.125(b) because: the substitute specification lacks a statement of excluding new matter and providing a marked-up copy. See MPEP 608.01(p).

Claim Objections

5. Claim 15 is objected to because of the following informalities: "mutual spacing" should be replaced with "spacing". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 13 are rejected because the limitations "irregular thickness" and "irregularly formed" are not clearly described. Irregular may be interpreted as "abnormal or unusual" or "lacking symmetry or evenness" as defined in Merriam-Webster's Collegiate Dictionary 10th Edition.

Claim 15 is rejected because the limitation "mutual spacing" is not clearly understood.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 2-7 and 11-14 rejected under 35 U.S.C. 102(b) as being anticipated by Callol et al. (EP 0824900).

Callol et al. discloses various non-uniform and uniform coatings for stents preventing interference between the coating and stent during radial expansion of the stent.

Regarding claims 2-4 and 13, a non-uniform or irregular patterned configuration having locations with no coating is described in lines 1-11 of column 7 (one or more discontinuous bands). Furthermore, note that a random pattern fulfills a patterned configuration.

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Regarding claims 5-7 and 11-14, gold coating islands of round shape and equal size are disclosed in lines 1-11 of column 7 (dots) and column 5, line 38 to column 6, line 5.

9. Claims 2-11 and 13-^{should be}₁₈ are rejected under 35 U.S.C. 102(e) as being anticipated by Yan (US PN 5,843,172).

Regarding claims 2-4, 11, and 13, a biocompatible and irregularly formed patterned-configuration surface coating having locations where the coating is missing completely is shown in figure 12. Note that base (108) is coated with multiple layers of coating islands progressively decreasing in size above and below the base (108). Furthermore, note that a random pattern fulfills a patterned configuration.

Regarding claims 5-7 and 14, substantially round coating islands of equal size are shown in figures 10 and 12.

Regarding claims 8, 15, and 17, figure 12 shows coating islands spaced farther apart where a greater degree of local stretching or expansion occurs. During radial expansion, the innermost layer coating islands (bottom, 112) will experience greater stress concentrations than the outermost layer coating islands (top, 110). More specifically, if the bottom layer (112) faces the vessel lumen and the upper layer (110) faces the vessel wall, the spacing between the coating islands adjacent to base (108) have greater spacing than the spacing between the outer coating islands (114).

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Regarding claims 9, 16, and 18, figure 12 also shows smaller coating islands (114) where greater degrees of local stretching occur (bottom, 112) as compared to coating islands adjacent to base (108).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (US PN 5,843,172) in view of Callol et al. (EP 0824900).

Yan meets the limitations of claims 12, as described above, but lacks or does not expressly disclose the coating islands comprising gold. However, Callol et al. teaches the use of gold for a radiopaque coating because of its resistance to cracking during deployment (lines 51-58 of column 4). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent coating taught by Yan to include gold in order to reduce the possibility of cracking during deployment.

Response to Arguments

1. Applicant's arguments filed June 6, 2002 have been fully considered but they are not persuasive.

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2. With regard to 102(b) rejection of claims 2-7 and 11-14 in view of Callol '900, Callol discloses a stent meeting the structural limitations of the claims. It is irrelevant as to the reason of providing the structure. Furthermore, having one or two coatings would still fulfill the limitations of Applicants coating.

3. With regard to the 102(e) rejection of claims 2-11 and 13-16 in view of Yan '172, the stent disclosed comprises a base layer with multiple layers or coatings surrounding both sides of the base layer. Each surrounding layer consists of round metal particles or coating islands. Variations are disclosed with respect to spacing and size that fulfill the structural limitations of the claims. Again, it is irrelevant as to the reason of providing the structure.

4. With regard to the 103(a) rejection of claim 12 over Yan '172 in view Callol '900, Yan fails to mention specific material options of the metal layers because the objective of the Yan '172 patent is to describe the novel aspects of the invention, specifically the porous features, sintered layers, and medication delivery methods. Whether the metal is stainless steel or gold would not have affected the object of the Yan '172 invention because the described process of making the stent would create the pores in either material.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

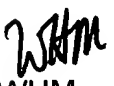
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


WHM
July 27, 2002


Paul B. Prebille
Primary Examiner